



Medical Chemical and Biological Defense Research



**Presented to the
Scientific Conference on Chemical and Biological Defense Research
6 March 2001**

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Report Documentation Page			Form Approved OMB No. 0704-0188	
<p>Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p>				
1. REPORT DATE 00 JAN 2002	2. REPORT TYPE N/A	3. DATES COVERED -		
4. TITLE AND SUBTITLE Medical Chemical and Biological Defense Research			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) U.S. Army Medical Research & Materiel Command			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release, distribution unlimited				
13. SUPPLEMENTARY NOTES This article is from ADA409494 Proceedings of the 2001 ECBC Scientific Conference on Chemical and Biological Defense Research, 6-8 March , Marriott's Hunt Valley Inn, Hunt Valley, MD., The original document contains color images.				
14. ABSTRACT				
15. SUBJECT TERMS				
16. SECURITY CLASSIFICATION OF: a. REPORT b. ABSTRACT c. THIS PAGE unclassified unclassified unclassified			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 21
19a. NAME OF RESPONSIBLE PERSON				



Medical Chemical/Biological Defense

Rationale for Investment

- ...the threat or use of NBC weapons is “a likely condition of future warfare.” **Quadrennial Defense Review (May 1997)**
- **Direct payoff of chemical/biological defense R&D:** Reduction, even elimination, of casualties which would otherwise follow a CW/BW attack.
- **Indirect payoffs:** Effective products against CW/BW deter employment and proliferation of CW/BW capabilities.
- **Efforts address Joint Service/CINC requirements**



Medical Chemical and Biological Defense Research Program Mission

- Provide medical solutions for military requirements to protect and sustain the force in a Chemical and/or Biological Warfare environment





MCBDRP Vision

- **To Preserve Total Warfighter Effectiveness on a CW/BW Battlefield**
 - ➲ Prevent casualties
 - ➲ Provide effective treatment of casualties for rapid return to duty
 - ➲ Provide rapid, far-forward diagnosis of CW/BW disease





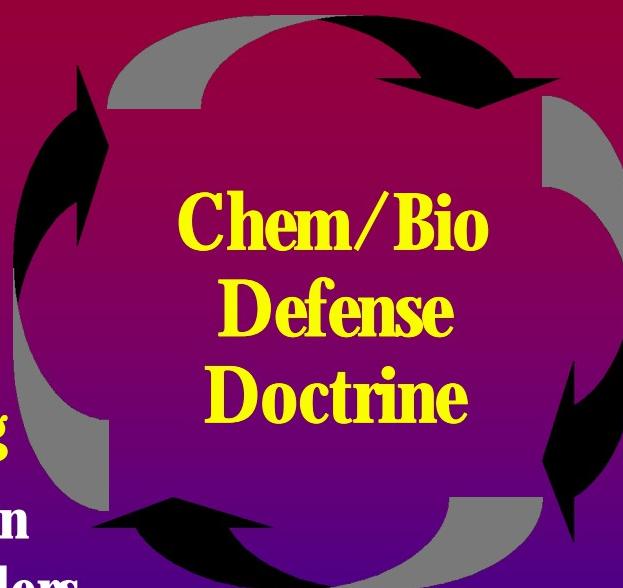
Protecting Warfighters Through Integration and Teamwork

Intelligence

- » Agent
- » Delivery System
- » Organization
- » Time

Education & Training

- » Military and Civilian Health Care Providers
- » Electronic Communication
- » Distance Learning



Medical Countermeasures

- » Vaccines & Prophylaxes
- » Diagnostics
- » Therapeutics

Physical Countermeasures

- » Detection
- » Physical Protection
- » Decontamination



Product Development Overview

Medical Products for
Chemical Agents

USAMMDA

Acquisition of Products for
Future Warfighters
Soldier, Biological and Chemical Command
JPO-BD/JVAP
Other Commodity Area Managers

Medical Products for
Biological Agents

JPO-JVAP

6.4 - 6.5 Advanced Development

- 6.3 Concept Exploration**
- 6.2 Applied Research**
- 6.1 Basic Research**



The “Tech Base” Products

- Basic Research Discoveries (Scientific Knowledge)
- Model Development for Agents of DoD Interest
- Vaccine/pretreatment Candidates
- Therapeutic Candidates
- Diagnostic Tests and Reagents
- Information
- Education
- Expertise & Consultation
- Technology Watch

Tech Base

Our Readiness Posture For Meeting Future Threats And Avoiding
Technological Surprise



Medical Biological Defense

- **Technical Approach:**
 - ➲ Identify mechanisms involved in disease process.
 - ➲ Develop and evaluate products (vaccines or drugs) to prevent or counter effects of biological toxins, bacteria, and viruses.
 - ➲ Develop methods to measure effectiveness of medical countermeasures in animal models which are predictive of human response.
 - ➲ Develop diagnostic systems and reagents.



Medical Biological Defense Organizational Taxonomy

MEDICAL BIOLOGICAL DEFENSE

Medical Countermeasures (MC) against BW Agents

DTO Efforts

- CB.24 MC for Encephalitis Viruses
- CB.25 Multiagent Vaccines for Biological Threat Agents
- CB.26 Common Diagnostic Systems
- CB.31 MC for Brucellae
- CB.32 Needleless Delivery Methods for Recombinant Protein Vaccines
- CB.33 Recombinant Protective Antigen (rPA) Vaccine Candidate
- CB.34 Recombinant Plague Vaccine Candidate

TASK AREAS

Vaccines

Therapeutics

Diagnostics



Medical Biological Defense Transitions

- **FY99/00**
 - ➲ Multivalent (A,B,C,E,F) Recombinant Botulinum Vaccine - MS I
 - ➲ Plague (F1-V) Antigen Vaccine - MS 0
 - ➲ Recombinant VEE Vaccine - MS 0
- **FY01**
 - ➲ Next Generation Anthrax Vaccine - MS I
 - ➲ Plague (F1-V) Antigen Vaccine - MS I
 - ➲ Common Diagnostics - MS 0
 - ➲ Multiagent Vaccine - MS 0
 - ➲ Brucella Vaccine - MS 0
 - ➲ Marburg (Filovirus) Vaccine - MS 0



Medical Biological Defense Products in Development (Projected Fielding)

- Q-Fever Vaccine – 2004 ?
- Smallpox Vaccine (Cell Culture Derived) - 2005
- Recombinant Plague Vaccine - 2006
- Venezuelan Equine Encephalitis Vaccine - 2008
- Tularemia Vaccine - 2008
- Recombinant Botulinum Vaccine - 2009
- Brucella Vaccine - 2010



Emerging Medical BD Products

- VEE/EEE/WEE Combined Vaccine
- Staphylococcal Enterotoxins Vaccine
- Ricin Vaccine
- Common Diagnostic System for BD Threats and ID Diseases
- Next Generation Anthrax Vaccine



Medical Biological Defense Investment in the Future

- Countermeasures for Genetically Engineered Microbes
 - ⌚ Genomic sequencing of BW threat agents to identify and understand virulence factors, toxins and drug resistance genes
- Immunomodulators and Therapies
 - ⌚ Alternatives to agent-specific vaccines or therapies
- Multiagent Vaccines
 - ⌚ Alternative to one vaccine for one BW threat agent



Strategic Challenges Medical Chemical and Biological Defense RDT&E

- Acquisition Model
- FDA Regulations
- Multiplicity of Threats

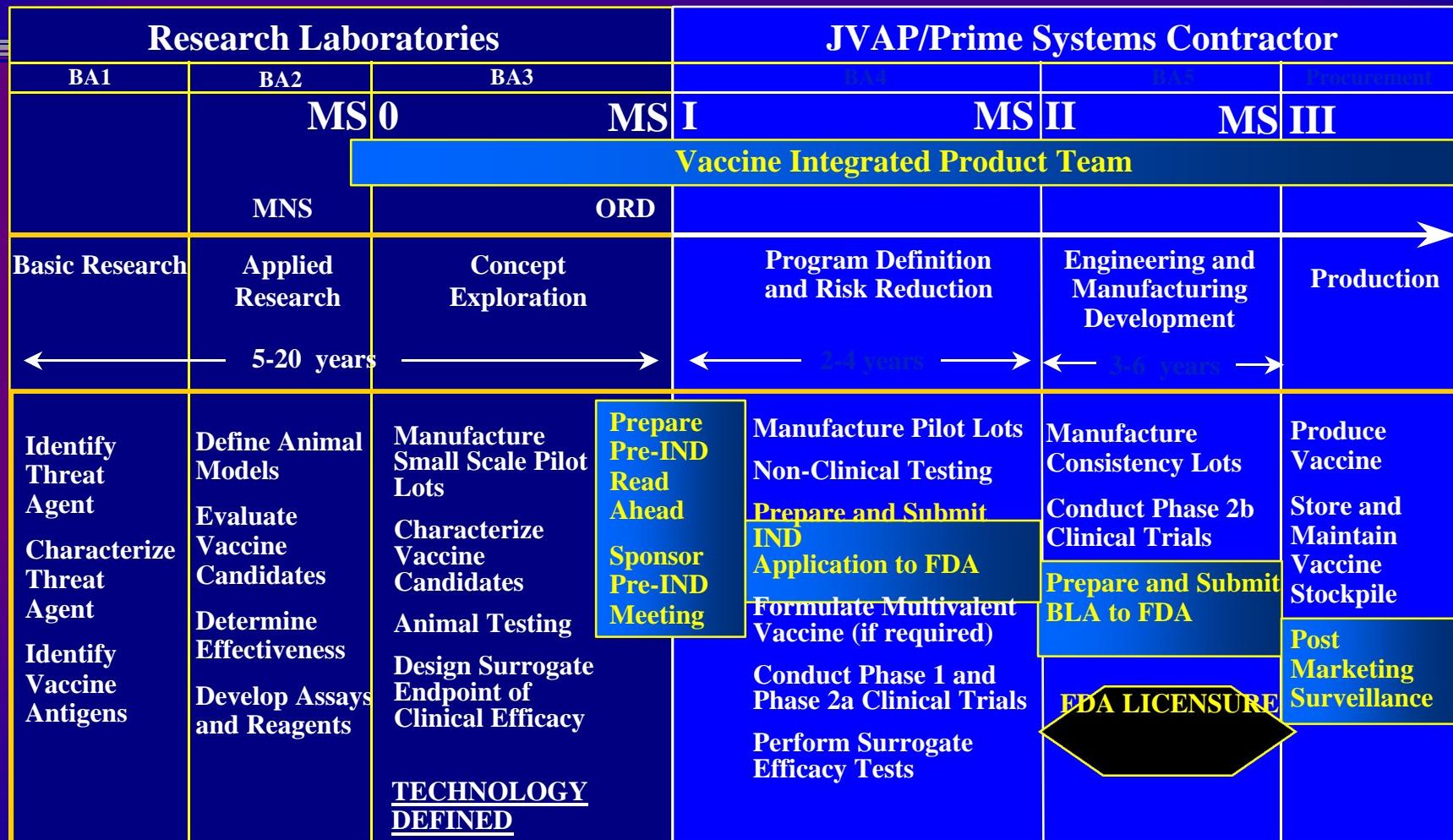


Strategic Challenges

- **Acquisition Model - Linear**
 - ➲ Old DoD 5000
 - ➲ New DoD 5000
 - ➲ Technology Readiness Levels
 - ➲ Risk Reduction
- **Biologicals/Pharmaceuticals – Recursive**
 - ➲ Iterative testing of numerous candidates
 - ➲ Kill products early
 - ➲ Finite lifetime

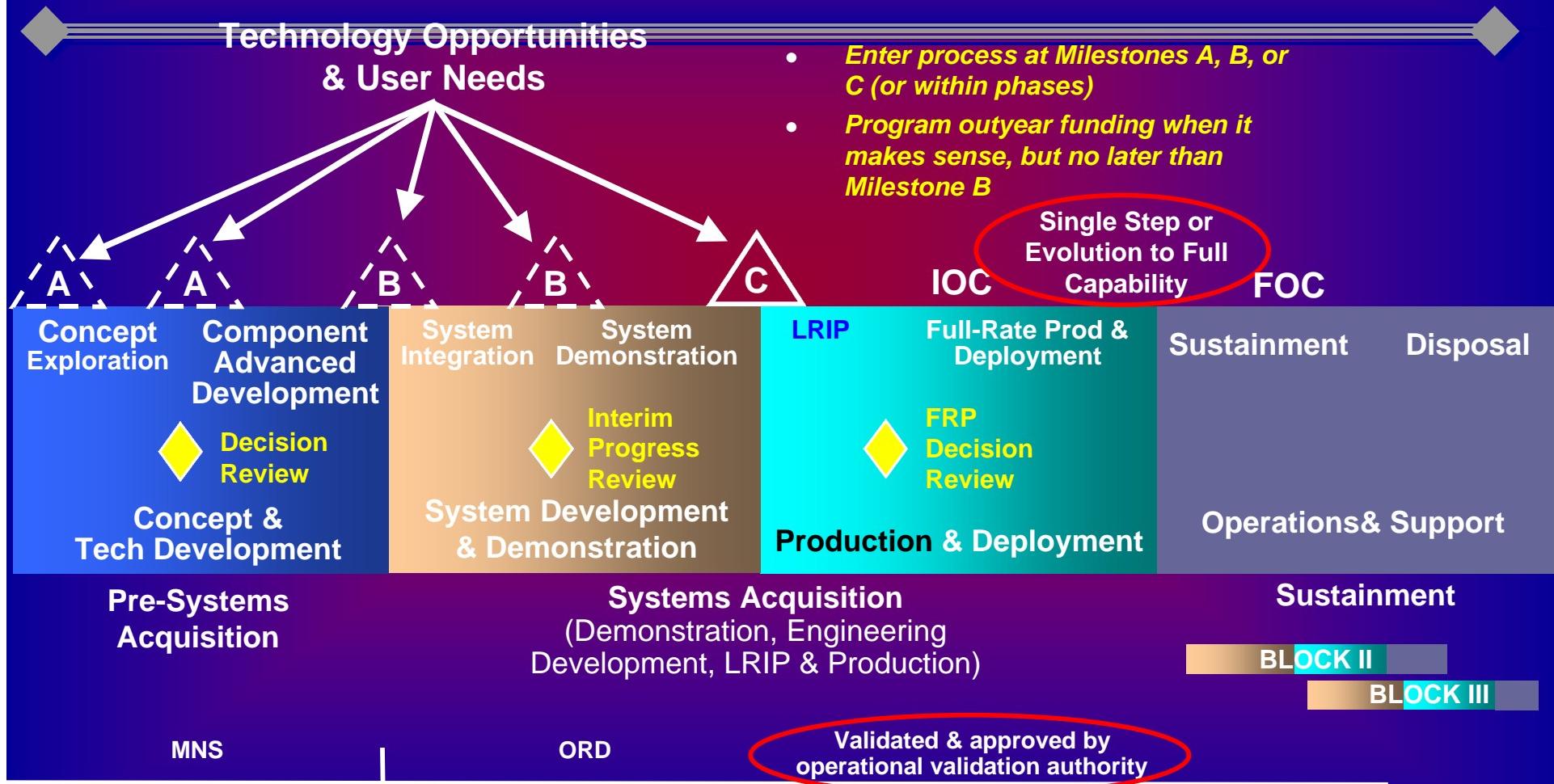


Integration of DoD Milestones and FDA Licensure Process





Defense Acquisition Management Framework





Strategic Challenges

- **FDA Regulatory Requirements**
 - ⌚ Products must be safe
 - ↳ Demonstrate in animals
 - ↳ Demonstrate in humans
 - ⌚ Products must be effective
 - ↳ Demonstrate in animals
 - ↳ Demonstrate in human clinical studies and field trials
- **Medical Chem/Bio Products – we can:**
 - ⌚ Demonstrate safety in animals and humans
 - ⌚ Demonstrate efficacy in animals
 - ⌚ Estimate efficacy in humans



Strategic Challenges

- **Proposed new FDA Rule**
 - ⌚ Allows consideration of animal efficacy studies in support of licensure request
 - ⌚ Additional requirements
 - ↳ Understand mechanisms of action of the disease-causing agent
 - ↳ Understand basis of action of the vaccine or drug
 - ↳ Demonstrate efficacy in two relevant animal models
 - ↳ Identify surrogate markers of efficacy



Strategic Challenges

- **Multiplicity of Threats**
 - ⌚ **Chemical Warfare Agents**
 - ↳ Nerve agents
 - ↳ Mustards
 - ↳ Blood/Choking agents
 - ⌚ **Biological Warfare Agents**
 - ↳ Viruses
 - ↳ Bacteria
 - ↳ Toxins
 - ⌚ **Emerging Threats**



Summary

- **Medical chemical and biological defense research presents unique challenges**
 - ⌚ Chemical threat agents
 - ⌚ Biological threat agents
 - ⌚ Medical regulatory compliance and DoD acquisition
- **We need cutting edge technologies to develop medical countermeasures for the warfighter**
 - ⌚ Biotechnology
 - ⌚ Informatics
 - ⌚ Genomics and Proteomics
- **Partnerships with the science community & industry are essential**
 - ⌚ CRADAs
 - ⌚ Contracts